No. 09-654

IN THE

Supreme Court of the United States

ORTHO BIOTECH PRODUCTS, L.P.,

Petitioner,

v.

UNITED STATES EX REL.
CHINYELU DUXBURY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

REPLY BRIEF FOR PETITIONER

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RULE 29.6 DISCLOSURE STATEMENT

The Petitioner, Ortho Biotech Products, L.P. ("OBP"), is a New Jersey corporation and subsidiary of parent corporation Johnson & Johnson, also a New Jersey corporation. No publicly held corporation other than Johnson & Johnson owns 10% or more of OBP's stock.

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REPLY BRIEF FOR PETITIONER

Respondent misinterprets this Court's decision in *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007), as resolving a circuit split on when a relator must provide the government with information supporting his suit's allegations to qualify as an original source. This split persists post-*Rockwell*, as evidenced by the Sixth and Ninth Circuits' continued reliance on pre-*Rockwell* precedents. Because "proper application of the [False Claims Act's ("FCA's")] public disclosure bar is critical to enforcement of that statute," Brief for the United States as Amicus Curiae, *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, No. 08-1409, at 3 (Aug. 28, 2008) ("United States Brief"), this Court should decide the issue now.

On Rule 9(b), Respondent does not even attempt to defend the First Circuit's "more flexible [pleading] standard" (Pet. App. 35a) for relators alleging that a "defendant induced *third parties* to file false claims with the government" (*id.* at 32a). Respondent contends instead that the Complaint here alleged "representative examples of false claims" (Opp. 3) and thus satisfied the stricter Rule 9(b) standard applied by other courts of appeals.

Respondent's refusal to defend the First Circuit's Rule 9(b) standard is not surprising, because, as explained in the Petition (pp. 24-26, 32), that standard is no more demanding than the Rule 8 notice pleading standard as construed by this Court in *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). And Respondent's assertion that the Complaint satisfied the stricter standard applied by other circuits is

plainly wrong. Contrary to Respondent's contentions, and as the First Circuit itself recognized, the Complaint identified *not one* false claim, much less a representative sample of such claims. Pet. App. 36a ("Duxbury does not identify specific claims.").

This case—in which the First Circuit held that Duxbury's satisfaction of its "more flexible standard" was "a close call" (Pet. App. 35a)—therefore presents an ideal vehicle for this Court to decide whether an FCA relator can satisfy Rule 9(b) without providing details about a single false or fraudulent claim, but merely by alleging facts sufficient "to strengthen the inference of fraud beyond possibility." *Id.* at 33a (internal quotation marks omitted). This "relaxed" Rule 9(b) standard—oddly available to relators *not* in a position to know whether false claims were actually filed, including the original relator here[1]—will only encourage more meritless and costly qui tam suits.

I. The Court Should Resolve A Circuit Split, Persisting After *Rockwell*, On When An Original Source Must Inform The Government Of Alleged Fraud.

1. Respondent contends (Opp. 11-19) that further review on the "original source" question is unwarranted because this Court in *Rockwell* purportedly resolved the circuit conflict on the issue.

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[1] On December 10, 2009, the district court allowed Chinyelu Duxbury to substitute as relator for her deceased spouse, original relator Mark Duxbury.

In *Rockwell*, however, this Court *expressly refused* to decide when an original source must inform the government of alleged fraud. *See* 549 U.S. at 476 ("Because [relator] did not have direct and independent knowledge of the information upon which his allegations were based, we need not decide whether [relator] met the second requirement of original-source status, that he have voluntarily provided the information to the Government before filing his action.").

Respondent is thus compelled to argue that *Rockwell* implicitly decided that an original source need not provide his information to the government before a public disclosure. Respondent contends that, in holding that the "information" about which an original source must have "direct and independent knowledge" is "complaint information and not 'public disclosure' information," the *Rockwell* Court relied on "the plain words of the statute requiring that the 'information' be provided to the government '*before filing an action.*'" Opp. 13. The *Rockwell* language italicized by Respondent, however, merely repeats statutory text known long before *Rockwell* by every court split over the "original source" issue presented here. And the fact that an original source must have direct and independent knowledge of the information underlying his action simply does not answer whether he must provide that information to the government before a public disclosure. As the United States explained post-*Rockwell*, requiring "a relator [to] come forward prior to a public disclosure best advances the FCA's twin goals of alerting the Government to potential fraud and creating incentives for relators to do so at the earliest possible time." United States Brief, at 23.

2. Because *Rockwell* did not resolve, expressly or implicitly, the "original source" question presented here, there is no reason to require special evidence that a circuit split on the issue persists post-*Rockwell*, as Respondent suggests. *See* Opp. 16-19. In any event, contrary to Respondent's assertions, post-*Rockwell* cases demonstrate that the split persists. Respondent acknowledges (Opp. 17-18) that Sixth and Ninth Circuit post-*Rockwell* cases—*i.e.*, *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503 (6th Cir. 2009), and *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195 (9th Cir. 2009)—restate positions that conflict with the First Circuit's holding on the "original source" issue. Respondent argues, however, that those decisions "do not provide serviceable precedent" (Opp. 16) perpetuating the conflict post-*Rockwell*, because the courts relied on pre-*Rockwell* interpretations of the "original source" provision only in dicta. Respondent is incorrect.

In *Meyer*, after citing *Rockwell*, the Ninth Circuit held that the district court did not err in denying relators "original source" status, 565 F.3d at 1201-03, *both* because the relators lacked "direct and independent knowledge" *and* because they had no "hand in the public disclosure of those allegations," *id.* at 1203—something they had to have if they informed the government of the alleged fraud after the public disclosure. Neither of those alternative bases for decision has any priority over the other and thus neither is dicta. "[W]here a decision rests on two or more grounds, none can be relegated to the category of obiter dictum." *Woods v. Interstate Realty Co.*, 337 U.S. 535, 537 (1949). *See also MacDonald, Sommers & Frates v. Yolo County*, 477 U.S. 340, 346

n.4 (1986) ("two stated reasons" for holding are "alternative bases of decision," not dicta).

The Sixth Circuit's *Poteet* decision similarly perpetuates the conflict. After citing *Rockwell*, the court concluded that the relator could not be an original source *both* because she did not inform the government of her allegations before filing suit *and* because she did not inform the government of the alleged fraud before its public disclosure. *See* 552 F.3d at 515.

The United States, the real party in interest in FCA cases, also remains, post-*Rockwell*, opposed to the First Circuit's approach. *See* United States Brief, at 22-24. *Rockwell* did not resolve the question presented, and seven circuits along with the United States remain split on the issue. *See* Pet. 16-21; *see also* John T. Boese, *Civil False Claims and Qui Tam Actions* § 4.02[D], at 4-114 (3d ed. 2009) (noting post-*Rockwell* "deep divisions" among circuits on "original source" question presented here).

3. It is clear, moreover, that the First Circuit's interpretation is incorrect. Respondent does not deny that, contrary to congressional intent, under the First Circuit's approach relators like Duxbury who piggyback on public disclosures and are thus not true "whistleblowers" can pursue an FCA action and demand a substantial share of any government recovery. *See* Pet. 22-23. Nor does Respondent deny that the First Circuit's approach makes requiring that an "original source" inform the government of alleged fraud of no practical effect. Another FCA provision, 31 U.S.C. § 3730(b)(2) (2006), already requires *all* relators to do that upon filing suit. *See* Pet. 23-24. The United States correctly construes

the "original source" exception, like the Sixth and D.C. Circuits, as requiring an original source to "disclose his information to the Government prior to a public disclosure." United States Brief, at 24.

II. The Court Should Review The First Circuit's Rule 9(b) Standard, Which Conflicts With Decisions Of This Court And Other Circuits And Encourages Meritless FCA Suits.

Respondent does not defend the First Circuit's "more flexible" Rule 9(b) standard, under which relators such as Duxbury need not plead specific details of any false claims but only allegations that "strengthen the inference of fraud beyond possibility." Pet. App. 33a. Instead, Respondent contends (Opp. 3) that the First Circuit used a different standard, consistently applied by other circuits, that requires pleading with particularity "representative examples" of false claims. Respondent is incorrect. The First Circuit plainly held that Duxbury's allegations passed muster only under its "more flexible standard." The decision thus provides this Court an excellent vehicle for reviewing the clear conflict between that standard and (1) this Court's precedents construing Rule 8 and (2) the approaches of other circuits that, as Respondent concedes (Opp. 3), require specifying "representative examples" of false claims.

1. Respondent contends that Petitioner "misleadingly suggest[ed]" that Duxbury did not identify any false claims (Opp. 2), but the First Circuit *expressly found* that he did not do so: "Duxbury does not identify specific claims." Pet. App. 36a. The First Circuit faulted the district court for requiring Duxbury to do so, explaining that there

is "a distinction between a qui tam action alleging that the defendant made false claims to the government, and a qui tam action in which the defendant induced *third parties* to file false claims." *Id.* at 32a (citation omitted). The First Circuit asserted that in cases involving "the latter context," such as Respondent's, the relator can satisfy Rule 9(b) merely "by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility'" without identifying false claims. *Id.* at 33a (internal quotation marks omitted).

The First Circuit then applied this "more flexible standard" and concluded that Duxbury's satisfaction of it was "a close call." Pet. App. 35a. The court asserted that Duxbury, while failing to "identify specific claims," provided enough "specifics" about Petitioner's alleged scheme—including the nature of the scheme (alleged kickbacks in the form of free drug samples and undisclosed rebates), the identity of some third parties who allegedly received kickbacks, and "the rough time periods" of the scheme, *id.* at 36a—"to strengthen the inference of fraud beyond possibility." *Id.* at 38a (internal quotation marks omitted). In so holding, the First Circuit highlighted as "instructive" an allegation that identified a facility that allegedly received free drug samples, while providing no details of any individual claim submitted as a result of the alleged "kickback." Pet. App. 35a (quoting Am. Compl. ¶ 211d). While the First Circuit concluded that allegations like this one sufficed to trigger an "inference of fraud beyond possibility," *id.* at 38a, they do not qualify as pleading a false claim with particularity. *See, e.g.*, *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir.

2006) (conclusory allegations insufficient for Rule 9(b)).

2. Thus, contrary to Respondent's contention (Opp. 3, 19-22), the First Circuit held that Duxbury satisfied its "more flexible [Rule 9(b)] standard," notwithstanding his *failure* to "identify specific [false] claims," Pet. App. 36a, much less a "representative cross-section of claims," Opp. 22. This standard wrongly measures the adequacy under Rule 9(b) of a relator's allegations based upon their *plausibility*, not their *particularity*. As explained in the Petition, *see* pp. 24-26, 32, that standard collapses Rule 9(b) into Rule 8, and thereby conflicts with this Court's precedent distinguishing Rule 9(b)'s heightened standard from Rule 8. *See Iqbal*, 129 S. Ct. at 1949, 1954; *Twombly*, 550 U.S. at 555-57. The First Circuit's adoption for FCA cases of a "flexible" Rule 9(b) standard no more stringent than "the less rigid . . . strictures of Rule 8," *Iqbal*, 129 S. Ct. at 1954, merits this Court's review.

3. The First Circuit's "flexible" standard also conflicts with the approach of other circuits that demand that relators provide details about actual false claims. The day after the petition was filed here, the Eleventh Circuit held that allegations that a defendant caused third parties to file false claims, in violation of 31 U.S.C. § 3729(a)(1), were deficient under Rule 9(b) because they did not "allege dates, times, or amounts of *individual* false claims" and "Rule 9(b) requires that *actual presentment of a claim* be pled with particularity." *Hopper v. Solvay Pharms., Inc.*, 588 F.3d 1318, 1326-27 (11th Cir. 2009) (emphases added). That holding squarely conflicts with the First Circuit's "more flexible

standard" for relators alleging that a defendant caused a third party to submit false claims.[2]

The Sixth and Eighth Circuits similarly require allegations identifying particular false claims and reject relaxing Rule 9(b) for relators lacking knowledge of, or access to, the billing practices of the party who allegedly submitted them. In *United States ex rel. Bledsoe v. Community Health Sys., Inc.*, the Sixth Circuit "h[e]ld that pleading an actual false claim with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)." 501 F.3d 493, 504 (6th Cir. 2007). While the Sixth Circuit explained that

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[2] In discussing what Rule 9(b) requires for allegations under 31 U.S.C. § 3729(a)(2) (2006), the Eleventh Circuit distinguished the First Circuit's decision here by asserting that Duxbury's intent allegations seemed more particularized. *See Hopper*, 588 F.3d at 1330-31. As noted in the Brief of Washington Legal Foundation as Amicus Curiae in Support of Petitioner, No. 09-654 (Jan. 4, 2010) ("WLF Brief"), at 13 n.3, that "does nothing to lessen the conflict" underlying the question presented here, which is whether a relator must allege particularized *false claims* under 31 U.S.C. § 3729(a)(1) and (2) (2006). The Court's resolution of that question as to § 3729(a)(1) would apply equally to its successor provision, § 3729(a)(1)(A) (2009), both of which create liability for knowingly causing the submission of false claims, and the Court's resolution as to § 3729(a)(2) would apply equally to its successor provision, § 3729(a)(1)(B) (2009), both of which require a "false statement or record" linked to a "false or fraudulent claim." *See* Pet. 3 n1. The FCA amendment in the Fraud Enforcement And Recovery Act Of 2009, Pub. L. No. 111-21, 123 Stat. 1617 (May 20, 2009), thus does not affect the importance of the Rule 9(b) question presented here.

relators pleading "complex and far-reaching fraudulent scheme[s]" need not identify "every false claim," the court held that they must "provide[] examples of specific false claims submitted to the government . . . representative . . . of the broader class of claims . . . to proceed to discovery on a fraudulent scheme." *Id.* at 510 (emphasis omitted). *See also United States ex rel. Lacy v. New Horizons, Inc.*, Civ. No. 08-6248, 2009 WL 3241299, at *3 (10th Cir. Oct. 9, 2009) (unpublished) (affirming dismissal of FCA claim for failing to allege a "single instance of a particular false claim . . . representative of the class described").

The Sixth Circuit, contrary to the First, also expressly rejected relaxing Rule 9(b) when "third parties possess information concerning the specific contracts at issue and the claims submitted for payment." *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 566 (6th Cir. 2003). The court explained that relaxing Rule 9(b) in FCA cases is unnecessary to protect the public "because the government's ability to intervene on the basis of information brought to its attention vindicates the public interest." *Id.* at 563. Indeed, because the government either possesses the relevant billing information or could obtain it, *see* WLF Brief, at 16 & n.4, the First Circuit's apparent justification for relaxing Rule 9(b) for a substantial category of relators lacks merit.

The Eighth Circuit similarly held that while relators need not provide "specific details of *every* alleged fraudulent claim" to satisfy Rule 9(b), they "must provide *some* representative examples." *Joshi*, 441 F.3d at 557.

Moreover, the Eighth Circuit in *Joshi* flatly rejected the relator's request to relax Rule 9(b) as the First Circuit did here. While recognizing that "the nature of Dr. Joshi's position with St. Luke's as an anesthesiologist, rather than as a member of St. Luke's billing or claims department, may not have made him privy to certain details relevant to his complaint and helpful to satisfying Rule 9(b)," the court held that "neither the Federal Rules nor the FCA offer any special leniency under these particular circumstances to justify Dr. Joshi failing" to meet the traditional Rule 9(b) standard. *Joshi*, 441 F.3d at 560 (brackets and internal quotation marks omitted). In rejecting the First Circuit's approach, under which relators such as Duxbury who lack first-hand knowledge of a third party's billing practices are exempted from the traditionally strict Rule 9(b) test, the Eighth Circuit noted the perversity of relaxing the test for someone, like Duxbury, claiming to have "direct and independent knowledge" of alleged fraud. *Id.* (citation omitted).

4. This Petition enables the Court to resolve conflicts over what Rule 9(b) requires for FCA suits. Rule 9(b) serves an important gate-keeping function in cases "understood to raise a high risk of abusive litigation," *Twombly*, 550 U.S. at 569 n.14—a function especially critical in FCA cases, where a plaintiff may pursue potentially breathtaking sums without having to show any injury. The threat of harassing "strike suits" and "fishing expeditions," *see Bledsoe*, 501 F.3d at 510, is thus particularly high in FCA cases, of which there recently has been "a surge." Brief Amicus Curiae of the American Hospital Association in Support of Petitioner, No. 09-654 ("AHA Brief"), at 20-21. The First Circuit's

"flexible standard" eviscerates Rule 9(b)'s mechanism for barring meritless but expensive and reputation-harming suits, which increasingly subject pharmaceutical companies and health care providers dealing with complex regulatory schemes to burdensome discovery and potentially ruinous liability. AHA Brief, at 20-22; WLF Brief, at 13-18. Petitioner should not have to suffer the harms Rule 9(b) is designed to prevent on the paradoxical ground that a relator professing to have "direct and independent knowledge" of FCA violations lacks information necessary to plead false claims with particularity.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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